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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/497,967	02/04/2000	Theodore G. Clark	235.00170101	8124
26813	7590	02/27/2004	EXAMINER	
MUETING, RAASCH & GEBHARDT, P.A. P.O. BOX 581415 MINNEAPOLIS, MN 55458			NAVARRO, ALBERT MARK	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/497,967

Applicant(s)

CLARK ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 10-15 and 17-36 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2, 12, 13, 15, 22 and 24-35 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5 and 36 is/are allowed.
- 6) ☒ Claim(s) 3, 4, 6, 10, 11, 14, 17-21 and 23 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 11/24/03.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

Applicants amendment filed October 8, 2003 has been received and entered. Consequently claims 1-6, 10-15, and 17-36 are pending in the instant application, of which claims 1-2, 12-13, 15, 22 and 24-35 have been withdrawn from further consideration as being drawn to a non-elected invention.

This application contains claims 1-2, 12-13, 15, 22 and 24-35 which are drawn to an invention nonelected with traverse in the response filed August 6, 2001. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

#### ***Claim Rejections - 35 USC § 101***

1. The rejection of claims 3-5, 10-11, 14, 17, 19 and 36 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of Applicants amendment.

#### ***Claim Rejections - 35 USC § 112***

2. The rejection of claims 6, 21 and 37 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a *T. thermophilla* host cell transformed with a heterologous DNA construct, does not reasonably provide enablement for a transgenic cell is withdrawn in view of Applicants amendment.

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3. The rejection of claims 3-4, 6, 10-11, 14, 17-21, and 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants are asserting that the nucleic acid molecule of claim 3 encodes "an antigenic portion of an I-antigen polypeptide having amino acid sequence SEQ ID NO: 7" and that the nucleic acid molecule of claim 4 encodes "a terminal membrane targeting portion of an I-antigen polypeptide having amino acid sequence SEQ ID NO: 7." Applicants assert that claims 3 and 4 also recite functional characteristics of the claimed nucleic acid molecules, specifically, the portion of SEQ ID NO: 7 that is encoded by the nucleic acid is "antigenic" (claim 3) or a "terminal membrane targeting" portion (claim 4). Applicants further assert that one of skill in the art can readily determine whether a nucleic acid molecule that possesses the recited structure also possesses the recited function by reference to the specification and/or the general knowledge in this highly skilled art.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the nucleic acid molecule of claim 3 encodes "an antigenic portion of an I-antigen polypeptide having amino acid sequence SEQ ID NO: 7" and that the nucleic acid molecule of claim 4 encodes "a terminal membrane

targeting portion of an I-antigen polypeptide having amino acid sequence SEQ ID NO: 7.” However, this information does not satisfy the written description requirements of 35 USC 112. Applicants specification sets forth of two representative proteins, i.e., SEQ ID NO: 7, which is the full length 55 kD I antigen and SEQ ID NO: 6, which is the full length 48 kD I antigen. Applicants specification does provide description of a single “fragment” of the 48 kDa antigen in which 19 amino acids at the Carboxy terminus are deleted and the resulting fragment is used to elicit an immune response. However, these examples do not provide “genus support” for claims which recite “at least about 60 amino acids” (Claim 3) or “at least about 10 amino acids” (Claim 4). Each of these claims encompasses nucleic acids encoding proteins with numerous changes permitted N terminally and C terminally. As stated previously, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus.

Finally Applicants assert that one of skill in the art can readily determine whether a nucleic acid molecule that possesses the recited structure also possesses the recited function by reference to the specification and/or the general knowledge in this highly skilled art. However, Applicants appear to be arguing that their invention is enabled, not that it meets the written description requirement. Given Applicants single example of one fragment of one full length protein, one of skill in the art would reasonably conclude

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that the disclosure fails to provide a representative number of species to describe the genus.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

4. The rejection of claims 3-4 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "at least about" is withdrawn.

5. The rejection of claim 10 under 35 U.S.C. 112, second paragraph, as vague and being indefinite in the recitation of "substantially complementary" is withdrawn in view of Applicants amendment.

6. The rejection of claim 11 under 35 U.S.C. 112, second paragraph, as vague and being indefinite in the recitation of "standard hybridization" is withdrawn in view of Applicants amendment.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The rejection of claims 4, 6, 14, 17, 19 and 21 under 35 U.S.C. 102(b) as being anticipated by Clark et al is maintained.

Applicants are asserting that Clark et al do not teach a 55 kDa antigen derived from an *I. multifilis* G5 isolate or a polynucleotide sequence encoding SEQ ID NO: 7. Applicants further assert that in comparing the sequence of Clark et al with a portion of SEQ ID NO: 7, there is only one common group of at least about 10 consecutive amino acids, which are nucleotides 165-176 of SEQ ID NO: 7. Applicants assert that nucleotides 165-176 are not located toward an extremity (i.e., a terminal portion) of a sequence of 468 nucleotides (SEQ ID NO: 7).

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are asserting that Clark et al do not teach a 55 kDa antigen derived from an *I. multifilis* G5 isolate or a polynucleotide sequence encoding SEQ ID NO: 7. However, Applicants are respectfully directed back to the rejected claims, none of them recite the limitations referred to, rather a "fragment" comprising at least about 10 amino acids. Consequently, this argument is not germane to the rejected claims.

Finally Applicants assert that in comparing the sequence of Clark et al with a portion of SEQ ID NO: 7, there is only one common group of at least about 10 consecutive amino acids, which are nucleotides 165-176 of SEQ ID NO: 7, and that nucleotides 165-176 are not located toward an extremity (i.e., a terminal portion) of a sequence of 468 nucleotides (SEQ ID NO: 7). First, Applicants will note that the sequence search (SEQ ID NO: 7) is of an amino acid sequence, not a nucleotide

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sequence. Furthermore, Applicants assert that amino acids 165-176 of a 468 amino acid protein are not located toward an extremity. However, what claim limitation are Applicants referring to? As stated previously, the claims require that the sequence comes from a "terminal membrane targeting portion." There is no structural requirement (SEQ ID NO) as to which specific amino acids make up this region. Consequently, the disclosure of Clark et al of a nucleotide sequence which encodes a protein comprising greater than 10 consecutive amino acids of SEQ ID NO: 7, which is located toward the terminus of the protein is deemed to anticipate the claimed invention.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

The following new grounds of rejection are applied to the amended claims:

***Claim Rejections - 35 USC § 102***

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Birkett et al.

The claim is directed to an isolated nucleic acid molecule that hybridizes with any of the nucleic acid molecules of claims 3-5 or 36 under conditions exemplified by about 150 mM NaCl, 15 mM trisodium citrate, and pH 7.6 at 55°C.

Birkett et al (US Patent 5,302,527) disclose of isolated random hexamer nucleic acids contained within a multiprime kit. (See column 15).



In view that the random hexamer kit disclosed by Birkett et al contains isolated nucleic acids which will hybridize to the sequences of the instant invention, and under the recited conditions, the disclosure of Birkett et al is deemed to anticipate the claimed invention.

Claims 5 and 36 are allowed.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro  
Primary Examiner  
February 19, 2004